



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY
AND POLLUTION PREVENTION

February 26, 2019

David J. Chi
Regulatory Affairs Manager
Monsanto company
800 North Lindbergh Blvd.
St. Louis, MO 63167

Subject: Labeling Notification per Pesticide Registration Notice (PRN) 98-10– Alternative brand names and/or primary brand names revisions and other minor changes
Product Name: MON 15985
EPA Registration Number: 524-522
Application Date: October 17, 2018
OPP Decision Number: 547096

Dear Mr. Chi:

The U.S. Environmental Protection Agency (EPA) is in receipt of your application for notification under Pesticide Registration Notice (PRN) 98-10 for the above referenced product. The Biopesticides and Pollution Prevention Division (BPPD) has conducted a review of this request for its applicability under PRN 98-10 and finds that the action requested falls within the scope of PRN 98-10.

The labeling submitted with this application has been stamped “Notification” and will be placed in our records. You must submit one (1) copy of the final printed labeling with the modifications.

Should you wish to add/retain a reference to your company’s website on your label, then please be aware that the website becomes labeling under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) and is subject to review by the EPA. If the website is false or misleading, the product will be considered to be misbranded and sale or distribution of the product is unlawful under FIFRA section 12(a)(1)(E). 40 CFR § 156.10(a)(5) lists examples of statements the EPA may consider false or misleading. In addition, regardless of whether a website is referenced on your product’s label, claims made on the website may not substantially differ from those claims approved through the registration process. Therefore, should the EPA find or if it is brought to our attention that a website contains false or misleading statements or claims substantially differing from the EPA-approved registration, the website will be referred to the EPA’s Office of Enforcement and Compliance Assurance.

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If you have any questions, please contact Michael Glikes of my team by phone at (703) 231-6499 or via email at glikes.michael@epa.gov.

Sincerely,

A handwritten signature in black ink, appearing to read 'Alan Reynolds', with a long horizontal flourish extending to the right.

Alan Reynolds, Team Leader
Emerging Technologies Branch
Biopesticides and Pollution
Prevention Division (7511P)
Office of Pesticide Programs

Enclosure

NOTIFICATION

524-522

The applicant has certified that no changes, other than those reported to the Agency have been made to the labeling. The Agency acknowledges this notification by letter dated:

02/26/2019

Plant-Incorporated Protectant Label

MON 15985

~~Bollgard II[®] Cotton~~

~~Bacillus thuringiensis subsp. kurstaki~~

~~Insect Control Protein~~

(OECD Unique Identifier: MON-15985-7)

Active Ingredients:

Bacillus thuringiensis Cry2Ab2 protein and the genetic material necessary for its production [PV-GHBK11] in event MON 15985 cotton ~~≤0.003~~ 0.009%*

Bacillus thuringiensis Cry1Ac protein and the genetic material necessary for its production [PV-GHBK04] in event MON 15985 cotton ~~≤0.00004~~ 0.00052%*

Other Ingredients:

Substance produced by the marker genes and the genetic material necessary for their production [PV-GHBK04 and PV-GHBK11] in event MON 15985 cotton ~~≤0.0022~~ 0.0304%*

*Percentage (wt/wt) on a dry weight basis.

~~PRECAUTIONARY STATEMENT~~

KEEP OUT OF REACH OF CHILDREN

CAUTION

~~Net (Contents)~~

~~[®]Bollgard II is a registered trademark of Monsanto Technology LLC.~~

EPA Registration Number 524-522

EPA Establishment Number 524-M0-002

Monsanto Company
800 North Lindbergh Blvd.
St. Louis, Missouri 63167

NET CONTENTS

DIRECTIONS FOR USE

It is a violation of federal law to use this product in a manner inconsistent with its labeling.

Cotton has been transformed to express the *Bacillus thuringiensis* subsp. *kurstaki* (*B.t.k.*) delta endotoxin CryIAc and Cry2Ab2 proteins for the control of the following lepidopteran cotton insect pests:

~~Bollgard II~~ MON 15985 cotton controls or suppresses the following cotton lepidopteran insect pests:

Tobacco Budworm	<i>Heliothis virescens</i>
Pink Bollworm	<i>Pectinophora gossypiella</i>
Cotton Bollworm	<i>Helicoverpa zea</i>
Cabbage Looper	<i>Trichoplusia ni</i>
Saltmarsh Caterpillar	<i>Estigmene acrea</i>
Cotton Leaf Perforator	<i>Bucculatrix thurbeiella</i>
Soybean Looper	<i>Pseudoplusia includes</i>
Beet Armyworm	<i>Spodoptera exigua</i>
Fall Armyworm	<i>Spodoptera frugiperda</i>
Yellowstriped Armyworm	<i>Spodoptera ornithogolli</i>
European Corn Borer	<i>Ostrinia nubilalis</i>

Transformed cotton must be accompanied by the Grower Guide which contains the following:

1. The *B.t.k* delta endotoxin proteins expressed in this cotton control the above listed lepidopteran cotton insect pests.
2. Routine applications of insecticides to control these insects are usually unnecessary when cotton containing the *B.t.k* delta endotoxin proteins is planted.
3. Instruction for growers to read the product Grower Guide prior to planting for information on planting, production and insect-resistance management.
4. ~~Bollgard II~~ MON 15985 must not be planted nor sold for commercial planting in Hawaii, Puerto Rico, U.S. Virgin Islands, and south of Route 60 (near Tampa) in Florida.

The following information regarding test plots and seed production must occur on bags of ~~Bollgard II~~ MON 15985 cotton seed intended for these purposes:

- a) Test plots or breeding nurseries, regardless of the plot size, established in Hawaii must not be planted within three miles of *Gossypium tomentosum* and must be surrounded by 24 border rows of a suitable pollinator trap crop.

- b) Experimental plots and breeding nurseries of ~~Bollgard II~~ MON 15985 cotton are prohibited on the U.S. Virgin Islands, and
- c) Test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico may be established without restriction if insecticide applications are used to effectively mitigate gene flow. Otherwise, established test plots or breeding nurseries, regardless of plot size, established on the island of Puerto Rico must not be planted within three miles of feral cotton and must be surrounded by 24 border rows of a suitable pollinator trap crop.

The following information regarding commercial production must be included in the Grower Guide:

In the states of Arizona, California, and New Mexico and in the following Texas counties: Brewster, Crane, Crockett, Culberson, El Paso, Hudspeth, Jeff Davis, Loving, Pecos, Presidio, Reeves, Terrell, Val Verde, Ward, and Winkler, all growers of ~~Bollgard II~~ MON 15985 cotton must employ one of the following structured refuge options:

1) External, Unsprayed Refuge:

Ensure that at least five acres of non-B. *t.k.* cotton (refuge cotton) is planted for every 95 acres of ~~Bollgard II~~ MON 15985 cotton. The size of the refuge must be at least 150 feet wide, but preferably 300 feet wide. This refuge may not be treated with sterile insects, pheromone, or any insecticide (except listed below) labeled for the control of tobacco budworm, cotton bollworm, or pink bollworm. At the pre-squaring cotton stage only, the refuge may be treated with any lepidopteran insecticide to control foliage feeding caterpillars. The refuge may be treated with acephate or methyl parathion at rates which will not control tobacco budworm or the cotton bollworm (equal to or less than 0.5 lbs. active ingredient per acre). The variety of cotton planted in the refuge must be comparable to ~~Bollgard II~~ MON 15985 cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to ~~Bollgard II~~ MON 15985 cotton. Ensure that a non-B.t.k. cotton refuge is maintained within at least ½ linear mile (preferably adjacent to or within ¼ mile or closer) from the ~~Bollgard II~~ MON 15985 cotton fields.

2) External Sprayed Refuge:

Ensure that at least 20 acres of non-B.t.k. cotton are planted as a refuge for every 80 acres of ~~Bollgard II~~ MON 15985 cotton (total of 100 acres). The variety of cotton planted in the refuge must be comparable to ~~Bollgard II~~ MON 15985 cotton, especially in the maturity date, and the refuge must be managed (e.g., planting time, use of fertilizer, weed control, irrigation, termination, and management of other pests) similarly to ~~Bollgard II~~ MON 15985 cotton. The non-B.t.k. cotton may be treated with sterile insects, insecticides (excluding foliar B.t.k. products) or pheromones labeled for control of the tobacco budworm, cotton bollworm, or pink bollworm. Ensure that a non-B.t.k. refuge is maintained within at least one linear mile (preferably within ½ mile or closer) from the ~~Bollgard II~~ MON 15985 cotton fields.

3) Embedded Refuge:

Plant the refuge cotton as at least one single non-*B.t.k.* cotton row for every six to 10 rows of ~~Bollgard II~~ MON 15985 cotton. The refuge may be treated with sterile insects, any insecticide (excluding foliar *B.t.k.* products), or pheromone labeled for the control of pink bollworm whenever the entire field is treated. The in-field refuge rows may not be treated independently of the surrounding ~~Bollgard II~~ MON 15985 cotton field in which it is embedded. The refuge must be managed (fertilizer, weed control, etc.) identically to the ~~Bollgard II~~ MON 15985 cotton.